Application No. 10/810,116 Art Unit: 3762

### **REMARKS**

Pursuant to the non-final Office Action pending claims 1-19 stand rejected. Following entry of this Reply, paragraph 002 of the specification is amended to correct the unintentional omitted claim to the initial priority document of the plurality of priority documents in the lineage of the application, claims 1, 9, 10, and 15 are amended, no claims canceled, and no new claims added. Thus, claims 1-19 are pending examination on the merits.

Applicants request entry of and favorable consideration of the amendments and remarks presented herewith.

# Objections Under 35 U.S.C. §112

Claims 1-19 stand objected to under 35 U.S.C. §112, second paragraph as being indefinite. Specifically, independent claims 1, 10 and 15 allegedly fail to set for appropriate antecedent basis for the phrase "each clause" recited in the third limitation recited therein. Claims 9 and 10 are rejected for incorrect dependency and vagueness, respectively.

Applicants herewith amend the independent claims (and thus all other pending dependent claims) to add the term "therapy" to the final paragraph of each said claim. Claim 9 is herewith amended to change the dependency from claim 6 to claim 7 as suggested by the Examiner. Claim 10 is amended to affirmatively recite the media upon which the instructions are encoded.

Applicants respectfully assert that the claims are now sufficiently definite and they particularly point out and distinctly claim the subject matter Applicants regard as the invention.

#### **Priority Claim**

The Examiner noted that the application claims and discloses subject matter from prior application serial no. 08/413,570 filed 30 March 1995 and thus may constitute a continuation or division of said prior application. Indeed, Applicants thank the Examiner for thoroughly reviewing the application and the

Art Unit: 3762

lengthy priority claim which someone unintentionally failed to list the initial priority application (now U.S. Pat. No. 5,545,186). Applicants respectfully request entry of the amendment to paragraph 002 of the specification as an unintentionally delayed submission according to 35 U.S.C. §120 and specifically authorizes the Examiner to debit Applicants Deposit Account for a fee necessary for entry of said amended specification.

### Claim Rejection Under 35 U.S.C. §102

Claims 1-6, 8, and 15-19 are rejected as anticipated by the '980 patent to Mehra (Mehra).

Applicants note that Mehra fails to include each and every claim limitation of the present claim set and thus fails to anticipate the claimed invention. For example, Mehra fails to teach, without limitation, the following limitation:

, wherein said highest priority rule continues to fire until one or more clauses of said highest priority rule are not satisfied for a predetermined sequence of R-R intervals.

Accordingly, the rejection based on Mehra should be properly withdrawn.

Claims 1-19 are rejected as anticipated by the '186 patent to Olson et al. (Olson).

Applicants herewith amend the specification to include appropriate reference to and priority claim from Olson; accordingly, Olson is not a competent reference vis-à-vis the pending claims and the rejection should be withdrawn.

Claims 1, 10 and 15 are rejected under 35 U.S.C. §102(f) because the applicant allegedly did not invent the subject matter as named inventor, Mark Brown, appears on the instant application but not on Olson. The Examiner maintains that claim 1 of Olson covers claims 1, 10 and 15.

Applicants aver that Olson does not appear to directly claim (at least at claim 1) the notion of using the "grammar" of the patient's heart which is recited in each independent claim hereof. As a result of this aspect of the present

Art Unit: 3762

claims, without limitation, Applicants assert that the present claims are potentially of different and potentially broader scope than Olson. Also, the amended claims include the notion of "sticky" rules wherein a then-highest-priority rule cannot be disqualified unless a predetermined sequence of cardiac cycles (e.g., three cycles) occurs with one or more false clauses within the rule structure. Support for this aspect of the invention can be found in the application as-filed as follows:

It should also be understood that rules 1-8 above are "sticky" rules, meaning that once a rule has fired, it will continue to fire until one or more clauses of the rule are not satisfied for a sequence of a predetermined number of R-R intervals. A nominal value for this predetermined number of R-R intervals is three, however, it is envisioned that the parameter may be programmable by the physician. This feature is intended to prevent a temporary violation of one of the clauses of a rule, for one or two beats, to override the firing of the rule. This is particularly important in the context of the rules intended to detect the likely occurrence of atrial tachycardias, where a one or two beat failure of the rule to be met could well result in the delivery of a ventricular anti-tachycardia therapy, in conjunction with the firing of a lower priority VT or VF detection rule, resulting in inappropriate delivery of ventricular anti-tachycardia therapy.

Claim 1 of Olson and claims 1, 10 and 15 (as amended) of the instant application are reproduced immediately below for the convenience of the Examiner.

1. An antiarrhythmia device comprising:

means for sensing depolarizations of heart tissue;

means for defining a plurality of prioritized rules capable of being simultaneously met, each of said rules defining at least one criterion based upon characteristics of sensed depolarizations of heart tissue, each said rule being met when the said at least one criterion of said rule is met, at least a first one of said rules when met indicating need for delivery of an antiarrhythmia therapy, at least a second one or said rules when met indicating that antiarrhythmia therapy should not be delivered;

means for analyzing said characteristics of said sensed polarizations to determine which of said rules are met;

means for determining the highest priority one of said rules which are met;

means responsive to at least said first one of said rules being the highest priority rule met, for delivering an antiarrhythmia therapy; and

Art Unit: 3762

means responsive to at least said second one of said rules being the highest priority rule met, for preventing delivery of an antiarrhythmia therapy.

1. (as amended) A processor-based method for determining whether to deliver or to withhold a cardiac rhythm management therapy in response to the occurrence of atrial and ventricular events, comprising:

sensing cardiac depolarization events;

determining a cardiac grammar based on the sensed events for a plurality of cardiac cycles;

applying a priority-rule based logic set to the cardiac grammar to determine if each of at least one clause that make up a plurality of discrete rules of said priority-rule based logic set is firing; and

withholding a cardiac rhythm management therapy or delivering the cardiac rhythm management therapy based on a highest priority rule of the priority-rule based logic set for which each of said at least one clause is firing, wherein said highest priority rule continues to fire until one or more clauses of said highest priority rule are not satisfied for a predetermined sequence of R-R intervals.

10. (as amended) A computer readable media for storing instructions for determining whether to deliver or to withhold a cardiac rhythm management therapy in response to the occurrence of atrial and ventricular events, comprising:

instructions encoded into a computer readable media for sensing cardiac depolarization events;

instructions encoded into the computer readable media for determining a cardiac grammar based on the sensed events for a plurality of cardiac cycles;

instructions encoded into the computer readable media for applying a priority-rule based logic set to the cardiac grammar to determine if each of at least one clause that make up a plurality of discrete rules of said priority-rule based logic set is firing; and

instructions encoded into the computer readable media for withholding a cardiac rhythm management therapy or delivering the cardiac rhythm management therapy based on a highest priority rule of the priority-rule based logic set for which each of said at least one clause is firing, wherein said highest priority rule continues to fire until one or more clauses of said highest priority rule are not satisfied for a predetermined sequence of R-R intervals.

15. (as amended) A system for determining whether to deliver or to withhold a cardiac rhythm management therapy in response to the occurrence of atrial and ventricular events, comprising:

means for sensing cardiac depolarization events;

means for determining a cardiac grammar based on the sensed events for a plurality of cardiac cycles;

Art Unit: 3762

means for applying a priority-rule based logic set to the cardiac grammar to determine if each of at least one clause that make up a plurality of discrete rules of said priority-rule based logic set is firing; and

means for withholding a cardiac rhythm management therapy or delivering the cardiac rhythm management therapy based on a highest priority rule of the priority-rule based logic set for which each of said at least one clause is firing, wherein said highest priority rule continues to fire until one or more clauses of said highest priority rule are not satisfied for a predetermined sequence of R-R intervals.

Since Olson fails to include specific claim coverage commensurate with the independent claims presented herewith to the extent that a species can be patented separately from a broader genus and the inventor of claimed features of said species can differ from a parent application having genus-type claims. Applicants assert that the ground of rejection has been overcome.

# Rejection Under 35 U.S.C. §102/§103

Claims 10-14 stand rejected as anticipated by or, in the alternative, obvious over Mehra.

Applicants respectfully assert that Mehra is devoid of any teaching or suggestion regarding what could be characterized as persistent rules ("sticky rules" per the specification) a limitation found in independent claim 10 as well as devoid of teaching, disclosure or suggestion regarding the limitations of dependent claims 11-14. As such the Examiner has failed to posit a prima facie obviousness rejection and the claims should now be deemed allowable.

### Rejection for Double Patenting (judicially created)

Claims 1-19 stand *provisionally* rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Pat. No. 5,545,186, claims 1-7 of U.S. Pat. No. 5,991,656, claims 1-10 of U.S. Pat. No. 6,259,947, claims 1-13 of U.S. Pat. No. 6,487,443, and claims 5-17 of U.S. Pat. No. 6,731,879.

Since the rejection is provisional in nature as none of the rejected claims has been identified as allowable, Applicants aver that no response is required.

Art Unit: 3762

That said, Applicants assert that the claims, both as previously presented and as now amended, are in fact patentably distinct and not rendered obvious by the cited patents.

In any event Applicants reserve the right to lodge a terminal disclaimer in the event that the Examiner persists in said rejection, should allowable claims be identified.

# Conclusion

Applicants assert that claims 1-19 are fully supported by the application as originally filed and no New Matter is introduced hereby.

There being no further outstanding objections or rejections, it is submitted that the application is in condition for allowance. An early action to that effect is courteously solicited. If the Examiner has questions or concerns regarding this response, a telephone call to the undersigned is encouraged and welcomed.

> Respectfully submitted, Attorney for Applicants

Date: 5 Jan 8

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